UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: Acetaminophen – ASD-ADHD Products Liability Litigation **This Document Relates To:** ***All cases***	**22md3043 (DLC)**

PLAINTIFFS' RESPONSE TO THE COURT'S JULY 11, 2024 ORDER TO SHOW CAUSE, DKT. 1496

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Rules

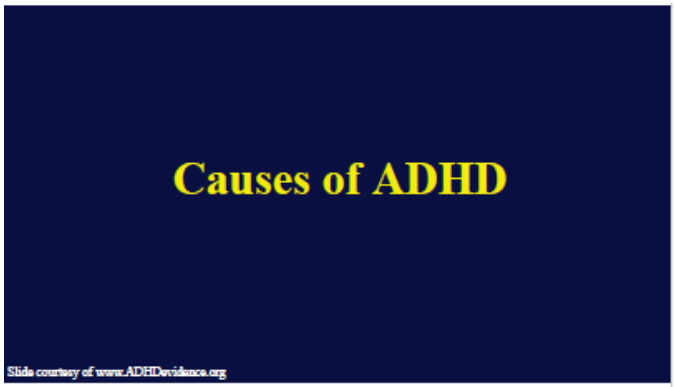
Other Authorities

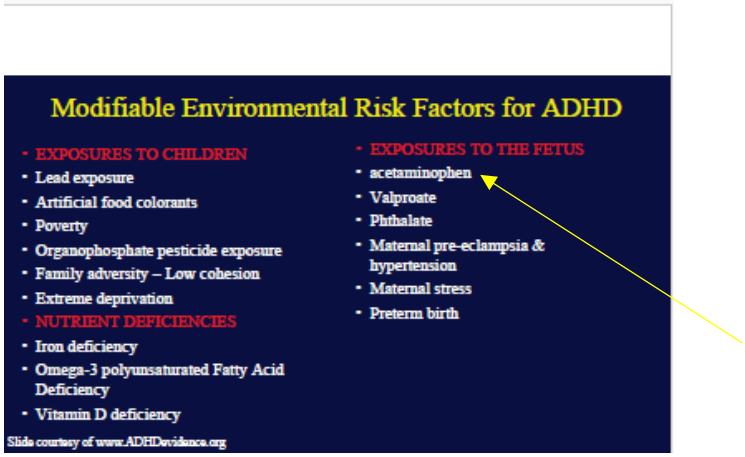
INTRODUCTION[1]

"[E]vidence-based findings that are unlikely to be overturned in the near future," Ex. 2, Faraone Dep. Tr. 363:10–12, include that "acetaminophen during pregnancy is associated with a 33 percent greater likelihood of ADHD in children," *id.* 363:19–364:2, and that "there's a dose-response relationship between maternal prenatal use of acetaminophen and ADHD," *id.* 367:21–368:1. Studies show "a weak, yet real association, between maternal use of acetaminophen while pregnant and subsequent ADHD . . . or ADHD symptoms in the exposed child." *Id.* 324:11–25. In fact, among all "environmental risk factors" for ADHD, *id.* 401:16–18, "the strongest evidence is for . . . exposure during the fetal period to . . . acetaminophen," *id.* 403:13–21. The studies

[1] This response is on behalf of Plaintiffs in the following actions: *Stokes et al. v. Johnson & Johnson Consumer Inc.*, 1:23-cv-11278; *Phippen et al. v. Johnson & Johnson Consumer Inc.*, 1:23-cv-11079; *Bordoy et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-693; *Day et al. v. Johnson & Johnson Consumer Inc. et al.*, 1:23-cv-11252; *Sims et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-1953; *Burke et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-1479; *Trigloff et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-0717; *Courington et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-1159; *Morrow et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-1322; *Roby et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-1343; *Bassett et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-1341; *Gilliam et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-1378; *Mikuski et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-1377; *Brown et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-1440; *Clark et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-3962; *Schnepp et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-03032; *Schnepp et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-03034; *Costello v. Johnson & Johnson Consumer Inc.*, 1:24-cv-03035; *Cornett v. Johnson & Johnson Consumer Inc.*, 1:24-cv-03036; *Brauer v. Johnson & Johnson Consumer Inc.*, 1:24-cv-03037; *Caldwell Parsons et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-03049; *McCormick et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-03038; *Stubblefield v. Johnson & Johnson Consumer Inc.*, 1:24-cv-03040; *Nangle v. Johnson & Johnson Consumer Inc.*,1:24-cv-03052; *Kellogg v. Johnson & Johnson Consumer Inc.*, 1:24-cv-03043; *Alexander et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-03044; *McCall v. Johnson & Johnson Consumer Inc.*, 1:24-cv-03056; *Lyken et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-03053; *Tillotson et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-03047; *Johnson v. Johnson & Johnson Consumer Inc.*, 1:24-cv-03027; *Stover v. Johnson & Johnson Consumer Inc.*, 1:24-cv-02340; *Farrow et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-04958, *Kobler et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-03039; *Barbee v. Johnson & Johnson Consumer Inc.*, 1:24-cv-00978, and *Webb et al. v. Johnson & Johnson Consumer Inc.*, 1:24-cv-04976.

reporting statistically significant results "all show a positive risk ratio," *id.* 470:21–471:4, which is "consistent with" "a positive risk" of ADHD due to prenatal acetaminophen exposure, *id.* 473:17–474:8. It makes "biological sense that acetaminophen exposure during pregnancy could cause ADHD." *Id.* 331:19–332:4. In presentation form:





Hearing and seeing that evidence, and drawing all inferences in Plaintiffs' favor, a reasonable jury could plainly conclude that prenatal exposure to acetaminophen can cause ADHD in offspring. And all of that evidence—and much more like it—is clearly admissible because it was produced by *Defendants'* own expert, Dr. Stephen Faraone. There is no pending motion to exclude his testimony. And the fact that he may endeavor to walk back his pro-Plaintiff testimony

is of no moment at this procedural posture. A jury could believe these "clarifications" are driven by his paid retention, and could instead credit his independent, prior-to-litigation position. Because it is more than arguable that Plaintiffs will prevail, summary disposition would improperly usurp the role of the fact finder.

BACKGROUND

Plaintiffs allege that prenatal exposure to Defendants' acetaminophen products can cause ADHD. Because Plaintiffs direct filed their cases after the Court's first *Daubert* Order, Dkt. 1381, they offered their own general causation expert, Dr. Roberta Ness. Dkt. 1404. Defendants moved to exclude her testimony. Dkt. 1461. On July 10, 2024, the Court granted Defendants' motion, Dkt. 1494, and its order to show cause followed, Dkt. 1496.[2]

Previously, Defendants disclosed seven experts, including Dr. Faraone, a psychiatrist specializing in ADHD. While being paid by Defendants, Dr. Faraone opined that prenatal exposure to acetaminophen cannot cause ADHD. Ex. 1, Faraone Am. Rep. at 4. But outside this litigation, Dr. Faraone repeatedly stated the opposite. For example:

- November 2015: Dr. Faraone was the senior author of a peer-reviewed article titled, "Oxidative Stress and ADHD: A Meta-Analysis," which "provide[d] preliminary, suggestive evidence that oxidative stress plays a role in the pathophysiology of ADHD." Ex. 4, Joseph et al. (2015) at 920.

- August 22, 2016: Dr. Faraone published a post on LinkedIn titled, "Does Acetaminophen use During Pregnancy Cause ADHD in Offspring?" His conclusion: **"There does seem to be a weak, yet real, association between maternal use of acetaminophen while pregnant and subsequent ADHD or ADHD symptoms in the exposed child."** Ex. 5, Faraone LinkedIn (2016) (emphasis added).

- October 31, 2017: Dr. Faraone published a post on LinkedIn titled, "ADHD and Acetaminophen use During Pregnancy," in which he highlights an epigenetic study showing that prenatal acetaminophen exposure "changes the fetal genome via a process

[2] Plaintiffs disagree with the Court's July 10 Order. Though this response shows that they nonetheless have sufficient, admissible evidence of causation, nothing is intended to waive any appellate arguments that excluding Dr. Ness's expert testimony was error.

called methylation. Such genomic changes could increase risk for ADHD." Ex. 6, Faraone LinkedIn (2017).

- 2019: Dr. Faraone served as an editor and chapter author of the World Federation of ADHD Guide. Ex. 7, Rohde et al. (2019). Dr. Faraone's chapter concludes that "environmental risk factor[s] must contribute to the etiology of ADHD," *id.* at 8, and "to fully understand the etiology of ADHD, we must consider how genes and the environment work together to cause the disorder." *Id.* at 10.

- May 18, 2020: Dr. Faraone republished his 2016 LinkedIn post on the website of the American Professional Society of ADHD and Related Disorders. Ex. 8, Faraone APSARD (2020).

- March 14, 2021: Dr. Faraone republished his 2016 LinkedIn post on his website, the ADHD Evidence Project. Ex. 9, Faraone ADHD Evidence Project Blog (Mar. 14, 2021). The website aims to "disseminat[e] and promot[e] scientifically researched and evidence-based conclusions about [ADHD] to patients, families and clinicians."[3]

- March 16, 2021: Dr. Faraone republished his 2017 LinkedIn post on the ADHD Evidence Project. Ex. 10, Faraone ADHD Evidence Project Blog (Mar. 16, 2021).

- September 2021: Dr. Faraone was the **lead author of "The World Federation of ADHD International Consensus Statement: 208 Evidence-based Conclusions About the Disorder"** (hereinafter the ADHD Consensus Statement), which collected "current and accurate information about ADHD supported by a substantial and rigorous body of evidence." Ex. 11, Faraone et al. (2021) at 792. This information includes studies showing that "**maternal use of acetaminophen during pregnancy was associated with a 33% greater likelihood of ADHD in their children,"** and **there is "a dose-response relationship between maternal prenatal use of acetaminophen and ADHD."** *Id.* at 795 (emphasis added). In addition, the ADHD Consensus Statement highlights that **"[m]ost cases of ADHD are caused by the combined effects of many genetic and environmental risks."** *Id.* at 792 tbl.1 (emphasis added).

- April 20, 2022: Dr. Faraone published a "set of slides [that] provides an overview of the diagnosis and treatment of ADHD" on his ADHD Evidence Project website.[4] Dr. Faraone **includes "acetaminophen" on a list of "exposures to the fetus" that constitute "[m]odifiable [e]nvironmental [r]isk [f]actors for ADHD."** Ex. 12, ADHD Evidence Project Presentation (2022) at 3 (emphasis added).

- July 2022: Dr. Faraone was the senior author of a peer-reviewed article entitled, "From Structural Disparities to Neuropharmacology: A Review of Adult Attention

[3] *Our Mission*, ADHD Evidence Project, https://www.adhdevidence.org/about (last visited July 20, 2024).

[4] *Slides to Download: ADHD 2022*, ADHD Evidence Project, https://www.adhdevidence.org/resources#slides (last visited July 25, 2024).

> Deficit/Hyperactivity Disorder Medication Treatment," which noted, "ADHD is most commonly caused by the cumulative effects of many genetic and environmental risks." Ex. 13, Khoury et al. (2022) at 345. **Among the environmental risk factors, "Faraone and colleagues" found "the strongest evidence" for "exposure during the fetal period to . . . acetaminophen," among other factors.** *Id.* (emphasis added).

During his deposition, Dr. Faraone vacillated between straightforwardly confirming these prior statements and engaging in tortured efforts to minimize them. On at least two occasions prior to this litigation, he identified acetaminophen as a cause of ADHD. *See id.* 358:14–21 (agreeing that study results showing increased risk of ADHD from prenatal acetaminophen exposure is an "evidence-based conclusion . . . regarding the *causes* of ADHD" (emphasis added)); *id.* 350:4–13 (describing list of "risk factors" within a slide presentation on the "causes of ADHD"); *see also* Ex. 11, Faraone et al. (2021) at 794 ("What causes ADHD?"); Ex. 12, ADHD Evidence Project Presentation (2022) at 2 ("Causes of ADHD").[5]

Earlier-filed plaintiffs moved to exclude Dr. Faraone, but the Court denied that motion as moot. Dkt. 1381 at 5. The Plaintiffs did not renew the earlier plaintiffs' motion.

ARGUMENT

Dr. Faraone will supply admissible evidence by which Plaintiffs can prove general causation under the applicable state laws. A reasonable jury could interpret his testimony and pre-litigation statements and research to find that prenatal exposure to acetaminophen can cause ADHD. Thus, there is a genuine issue of material fact as to causation. The Court should permit Plaintiffs' actions to proceed and allow a jury to consider this admissible evidence.

[5] Even after preparing his report and testifying for Defendants, Dr. Faraone continued to publish peer-reviewed literature that supports general causation and contradicts his opinions in this litigation. For instance, in June 2024, Dr. Faraone published a "consensus statement" on "standard outcome measures for neurodevelopmental disorders," concluding that use of validated non-diagnostic outcome measures "has the potential to improve clinical practice and research." Ex. 3, Mulraney et al. (2024) at 10. He emphasized, contrary to his expert report, that "it is important to work transdiagnostically in the NDD field." *Id.* at 2.

I. Legal Standard

Summary judgment is appropriate "only where there is no genuine issue of material fact to be tried." *Moll v. Telesector Res. Grp., Inc.*, 94 F.4th 218, 228 (2d Cir. 2024) (quoting *Kaytor v. Electric Boat Corp.*, 609 F.3d 537, 545 (2d Cir. 2010). "The court's role is 'not to resolve disputed questions of fact but solely to determine whether, as to any material fact, there is a genuine issue to be tried.'" *Valerio v. Metro. Transp. Auth.*, No. 23cv1938 (DLC), 2024 WL 2305386, at *4 (S.D.N.Y. May 20, 2024) (Cote, J.) (quoting *Moll*, 94 F.4th at 227). "In determining whether genuine issues of fact exist, the court must 'review the record taken as a whole' and 'must draw all reasonable inference in favor of the nonmoving party.'" *Id.* (quoting *Moll*, 94 F.4th at 227). To defeat summary judgment, the nonmoving party must "make a sufficient showing" by pointing to "admissible materials in the record [that] *make it arguable* that the claim has merit[.]" *Id.* (emphasis added) (quoting *Moll*, 94 F.4th at 227). That showing can be made by "citing to particular parts of materials in the record, including depositions, documents, . . . or other materials." Fed. R. Civ. P. 56(c)(1)(A); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986).

Admissible "materials in the record" includes "the deposition testimony" of adverse expert witnesses. *Lutz v. Estate of Hillier*, 574 F. Supp. 1032, 1034 (S.D. W. Va. 1983). To oppose summary judgment based on that source of evidence, it of course must be sufficient to allow a reasonable jury to "sustain [plaintiffs'] burden." *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 387 F. Supp. 3d 323, 351 (S.D.N.Y. 2019), *aff'd*, 982 F.3d 113 (2d Cir. 2020). Seizing "on a single line" of deposition testimony, or drawing unreasonable inferences from the evidence, of course will not suffice. *Id.* But where the totality of evidence is susceptible to more than one interpretation and requires a credibility determination, binding precedent has long entrusted the question to jurors. *E.g. Colby v. Klune*, 178 F.2d 872, 873 (2d Cir. 1949).

II. Plaintiffs Can Establish General Causation Based on Dr. Faraone's Testimony and Related Documentary Evidence.

Plaintiffs can satisfy their burden to prove general causation through admissible evidence emanating from Dr. Faraone's testimony. Viewing the evidence in the light most favorable to plaintiffs, a jury could reasonably discredit Dr. Faraone's made-for-litigation opinions and find that his testimony and non-litigation statements prove that acetaminophen can cause ADHD.

A. Plaintiffs Are Entitled To Call Dr. Faraone To Testify About General Causation.

As an initial matter, Plaintiffs are entitled to call Dr. Faraone as an expert witness at trial. *See Al Hirschfeld Found. v. Margo Feiden Galleries Ltd.*, No. 16 Civ. 4135 (PAE), 2020 WL 598615, at *2 (S.D.N.Y. Feb. 7, 2020) (holding plaintiff "is entitled to call the witnesses of its choosing, including adverse witnesses affiliated with [defendant]"). Defendants offered Dr. Faraone as an expert witness, so they are estopped from contesting the admissibility of his opinions. Plaintiffs here have not moved to exclude Dr. Faraone.

Before he was paid by Defendants to disclaim general causation, Dr. Faraone concluded time and again that prenatal acetaminophen exposure can cause ADHD, as described *supra*. He never retracted any of these statements, *see, e.g.*, Ex. 2, Faraone Dep. Tr. 357:11–13, and many of them remain *publicly available*.[6] The only time Dr. Faraone has ever opined that acetaminophen does not cause ADHD is when he is being paid to testify for Defendants. It is for the jury to decide whether that paid testimony is more credible than Dr. Faraone's prior body of scientific work. *Colby*, 178 F.2d at 873 ("When . . . ascertainment . . . of the facts of a case turns on credibility, a triable issue of fact exists, and the granting of a summary judgment is error.").

[6] For example, Exhibit 5 remains available online at https://www.linkedin.com/pulse/does-acetaminophen-use-during-pregnancy-cause-adhd-faraone-ph-d-/ (last visited July 25, 2024); Exhibit 6 is available at https://www.linkedin.com/pulse/adhd-acetaminophen-use-during-pregnancy-stephen-faraone-ph-d-/ (last visited July 25, 2024); and Exhibit 12 is available at https://www.adhdevidence.org/resources#slides (last visited July 25, 2024).

B. Evidence Relating To Dr. Faraone's Expert Testimony Is Admissible.

Each and every one of Dr. Faraone's prior statements described *supra* is admissible under the Federal Rules of Evidence. *First*, Dr. Faraone's prior statements in deposition and published literature are plainly relevant. *See* Fed. R. Evid. 401. It is thus admissible under Federal Rule of Evidence 402. It has substantial probative value in establishing that acetaminophen can in fact cause ADHD that is not outweighed by any of the Rule 403 considerations. Fed. R. Evid. 403. Further, Dr. Faraone indisputably has personal knowledge of his own deposition testimony, prior publications, and other public statements. Fed. R. Evid. 602. He admitted as much regarding his prior publications and public statements during his deposition. *See, e.g.*, Ex. 2, Faraone Dep. Tr. 79:5–8; *id.* 150:14–17.

Second, Dr. Faraone's deposition testimony about his prior research and public statements relating to general causation are not hearsay under Federal Rule of Evidence 801(d)(1). This testimony was "given under penalty of perjury . . . in a deposition." Fed. R. Evid. 801(d)(1)(A); *see also* Ex. 2, Faraone Dep. Tr. 14:21–25 (swearing in the witness). Dr. Faraone testified that in peer-reviewed literature he identified, among all "environmental risk factors" for ADHD, Ex. 2, Faraone Dep. Tr. 401:16–18, "the strongest evidence is for . . . exposure during the fetal period to . . . acetaminophen," *id.* 403:13–21. And he testified that the studies looking at the link between acetaminophen and ADHD that reported statistically significant results "all show a positive risk ratio," *id.* 470:21–471:4, which is "consistent with" "a positive risk" of ADHD due to prenatal acetaminophen exposure, *id.* 473:17–474:8. And these results "make biological sense, that acetaminophen exposure during pregnancy could cause ADHD." *Id.* 331:19–332:4. To be sure, in his expert report, Dr. Faraone opined that "there is no valid association," the studies "yielded inconsistent results," and "there is no basis to conclude" that acetaminophen could biologically cause ADHD. Ex. 1, Faraone Am. Rep. at 95, 97. All of Dr. Faraone's inconsistent statements at

his deposition in this case are admissible evidence that may be used "for substantive purposes," including establishing general causation. *See Santos v. Murdock*, 243 F.3d 681, 684 (2d Cir. 2001).

Third, Dr. Faraone's statements in peer-reviewed scientific literature are independently admissible under the learned treatise exception to the hearsay rule. Fed. R. Evid. 803(18). That rule permits the reading into evidence of "statement[s] contained in a treatises, periodical or pamphlet if: (A) the statement is called to the attention of an expert witness . . . ; and (B) the publication is established as a reliable authority by the expert's admission or testimony . . . ." *Id.* Here, the statements at issue were called to Dr. Faraone's attention during his deposition, and his testimony establishes that they are reliable authority. Ex. 2, Faraone Dep. Tr. 358:8–368:9, 417:25–421:15, 357:6–10, 159:14–165:16, 183:15–186–20, 137:7–155:2, 281:8–285:12, 168:19–170:24, 399:3–416:20. This Court has recognized that "articles . . . mentioned in the deposition testimony of the expert witness[]" may be considered by courts for purposes of satisfying Plaintiffs' burden on summary judgment. *Knight v. Dep't of Corrs.*, No. 18-CV-7172 (KMK), 2022 WL 1004186, at *8 (S.D.N.Y. Mar. 30, 2022).

Finally, any of Dr. Faraone's prior statements that may constitute hearsay, such as his LinkedIn posts, blog posts, and slide presentation, are admissible for purposes of impeachment. *Santos*, 243 F.3d at 684 (prior inconsistent statements not "made at a trial, hearing, or other proceeding, or in a deposition" "are generally admissible for impeachment purposes only") (internal quotation marks and citation omitted). *Combined* with other substantive evidence that supports general causation, the impeachment evidence contradicting Dr. Faraone's opinion that acetaminophen *cannot* cause ADHD creates a genuine issue of material fact.

C. Evidence Relating To Dr. Faraone Is Sufficient To Defeat Summary Judgment.

Given the sheer number of Dr. Faraone's inconsistent statements coupled with his published pre-litigation statements, a reasonable jury could conclude that prenatal exposure to

acetaminophen can in fact cause ADHD. The Faraone evidence, construed in the light most favorable to Plaintiffs, can reasonably support the following factual findings: (1) there is a positive and statistically significant association between prenatal acetaminophen exposure and ADHD; (2) there is a dose-response relationship between acetaminophen exposure and ADHD; (3) it "makes biological sense" that prenatal acetaminophen exposure can cause ADHD; (4) environmental risk factors play a role in causing ADHD; and (5) acetaminophen is one of the environmental risk factors that plays a role in causing ADHD. A jury need not even draw inferences to make these five findings. It need only credit direct, admissible statements of scientific opinion Dr. Faraone himself wrote or said. It is therefore well within the province of a reasonable jury to draw the inference that prenatal exposure to acetaminophen can cause ADHD. And because it is at the least "arguable" that Plaintiffs can establish general causation, summary judgment must be denied. *Valerio*, 2024 WL 2305386, at *4 (quoting *Moll*, 94 F.4th at 227).

CONCLUSION

As set forth herein, Plaintiffs are entitled to rely on admissible expert evidence to show general causation and oppose summary judgment. Fed. R. Civ. P. 56(c)(1)(A). Dr. Faraone's adverse testimony and documentary evidence is more than sufficient to establish that prenatal acetaminophen exposure can cause ADHD in children. The Court should not enter summary judgment and should permit Plaintiffs to proceed on this record.

Dated: July 25, 2024

Respectfully submitted,

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